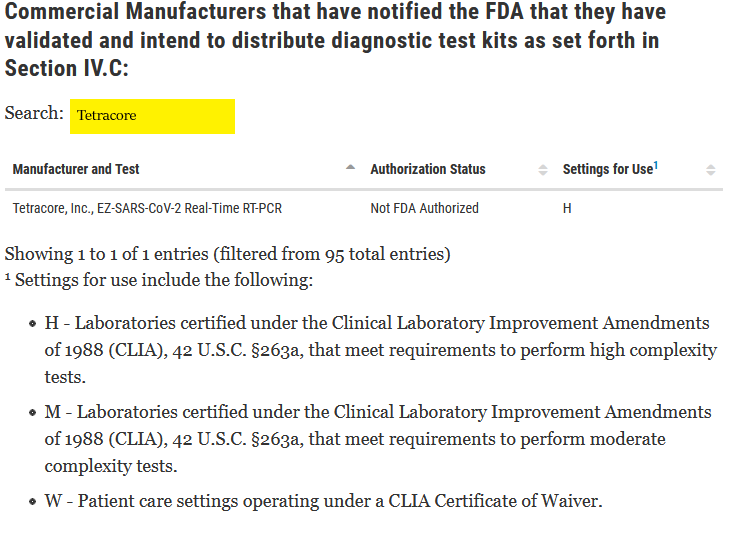
**Notifications and Emergency Use Authorizations: FAQs on Testing for SARS-CoV-2**

# [**https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/notifications-and-emergency-use-authorizations-faqs-testing-sars-cov-2#5fc7c1f1492e4**](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/notifications-and-emergency-use-authorizations-faqs-testing-sars-cov-2#5fc7c1f1492e4)

**Select the following question:**  [**Q: What commercial manufacturers are distributing diagnostic test kits under the policy outlined in Section IV.C of the Policy for Coronavirus Disease-2019 Tests? (Updated 12/18/20)**](file:///C:\Users\rrauh\Desktop\Notifications%20and%20Emergency%20Use%20Authorizations%20FAQs%20on%20Testing%20for%20SARS-CoV-2%20FDA.html#5fdd25155b769)

**Enter Tetracore into the search bar:**

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**Below is the complete answer with the Tetracore Test highlighted:**

A: As stated in Section IV.C of the FDA's [*Policy for Coronavirus Disease-2019 Tests*](file:///C:\regulatory-information\search-fda-guidance-documents\policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised), the FDA does not intend to object to a commercial manufacturer's development and distribution to clinical laboratories of diagnostic test kits to perform assays to detect SARS-CoV-2 for a reasonable period of time after the manufacturer's validation of the test and while the manufacturer is preparing its EUA request where the manufacturer provides instructions for use of the test and posts data about the test's performance characteristics on the manufacturer's website. Transparency can help mitigate potential adverse impacts from a poorly designed test by facilitating better informed decisions by potential purchasers and users. As noted in the guidance, the believes that 15 business days is a reasonable period of time to prepare an EUA submission for a test whose performance characteristics have already been validated. Unless and until an EUA is issued that authorizes additional testing environments for a specific test, under CLIA, use of that test is limited to laboratories certified to perform high-complexity testing, including testing at the point-of-care when the site is covered by the laboratory's CLIA certificate for high-complexity testing. This policy does not apply to at home testing, including at-home specimen collection.

The commercial manufacturers listed below have notified FDA that they have validated and intend to distribute diagnostic test kits as set forth in Section IV.C of the FDA's [*Policy for Coronavirus Disease-2019 Tests*](file:///C:\regulatory-information\search-fda-guidance-documents\policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised). Where the Authorization Status is "FDA Authorized," the FDA reviewed and issued an EUA for the test after notification was given. Where the Authorization Status is shown as "Not FDA Authorized," the FDA has not yet reviewed the manufacturer's validation and issued an EUA for the test, and the test is included in this list to provide transparency regarding the notification submitted to FDA. The "Setting for Use" designation of "H" refers to a laboratory certified under CLIA to perform high-complexity testing. Certain developers have completed the EUA process prior to offering a test for clinical use rather than notify FDA under this policy. Tests that have been issued an EUA can be found on the [EUA page](file:///C:\medical-devices\coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices\vitro-diagnostics-euas).

If an EUA request is not submitted within a reasonable period of time, or if significant problems are identified with a test and cannot be addressed in a timely manner, the FDA intends to remove the manufacturer and test from this list, would expect the manufacturer to suspend distribution and conduct a recall of the test, and may take additional actions as appropriate.

**Commercial Manufacturers that have notified the FDA that they have validated and intend to distribute diagnostic test kits as set forth in Section IV.C:**

| **Manufacturer and Test** | **Authorization Status** | **Settings for Use**[**1**](file:///C:\Users\rrauh\Desktop\Notifications%20and%20Emergency%20Use%20Authorizations%20FAQs%20on%20Testing%20for%20SARS-CoV-2%20FDA.html#ivcnote) |
| --- | --- | --- |
| BD BioGx SARS-CoV-2 Reagents for BD MAX System | [FDA Authorized](file:///C:\media\136650\download) | H, M |
| Biomeme, Inc. Biomeme SARS-CoV-2 test kit | [FDA Authorized](file:///C:\media\141049\download) | H |
| BGI Genomics Co. Ltd | [FDA Authorized](file:///C:\media\136473\download) | H |
| ChromaCode, Inc. HDPCR SARS-CoV-2 Assay | [FDA Authorized](https://www.fda.gov/media/138787/download) | H |
| Co-Diagnostics, Inc. | [FDA Authorized](file:///C:\media\136684\download) | H |
| Genomictree, Inc. AccuraDTect SARS-CoV-2-qPCR Kit | Not FDA Authorized | H |
| OPTOLANE Technologies Inc. Kaira 2019-nCoV Detection Kit | [FDA Authorized](file:///C:\media\141792\download) | H |
| OSANG Healthcare Co., Ltd, GeneFinder COVID-19 Plus RealAmp Kit | [FDA Authorized](file:///C:\media\137113\download) | H |
| QIAGEN QIAstat-Dx Respiratory SARS-CoV-2 Panel Assay | [FDA Authorized](file:///C:\media\136569\download) | H, M |
| YD Diagnostics Corp. MolecuTech Real-Time COVID-19 | Not FDA Authorized | H |
| LabGenomics, Co., Ltd. LabGun™ COVID-19 Assay kit | [FDA Authorized](file:///C:\media\137484\download) | H |
| VelaDx ViroKey™ SARS-CoV-2 RT-PCR Test | [FDA Authorized](https://www.fda.gov/media/140919/download) | H |
| Hologic, Inc. Aptima SARS-CoV-2 assay | [FDA Authorized](https://www.fda.gov/media/138097/download) | H |
| GeneOne Diagnostics Corporation COVID-19 Nucleic Acid Diagnostic Kit | Not FDA Authorized | H |
| RTA Labs DIAGNOVITAL SARS-CoV-2 | [FDA Authorized](https://www.fda.gov/media/138929/download) | H |
| Solgent Co. Ltd., COVID-19 DiaplexQ Diagnostic Kit | [FDA Authorized](https://www.fda.gov/media/138306/download) | H |
| ZhuHai Sinochips Bioscience Co., Ltd COVID-19 Real-time PCR Test Kit | [FDA Authorized](file:///C:\media\141243\download) | H |
| GeneReach Biotechnology Corporation POCKIT Central SARS-CoV-2 | Not FDA Authorized | H |
| American BioSources Inc., DBA Genomic Diagnostics GDx GrandPerformance SARS-CoV-2 Detection Kit | Not FDA Authorized | H |
| Taigen Bioscience Corporation LabTurbo AIO COVID-19 RNA Testing kit | Not FDA Authorized | H |
| Gencurix Inc. GenePro SARS-CoV-2 Test | [FDA Authorized](https://www.fda.gov/media/139443/download) | H |
| ELITechGroup MDx LLC SARS-CoV-2 ELITe MGB Assay | Not FDA Authorized | H |
| Agena Bioscience SARS-CoV-2 Panel | Not FDA Authorized | H |
| Grifols Diagnostic Solutions Inc. Procleix SARS-CoV-2 Assay | Not FDA Authorized | H |
| MiCo BioMed Co., Ltd. Veri-Q COVID-19 Multiplex Detection Kit | Not FDA Authorized | H |
| Fluidigm Corporation Advanta Dx SARS-CoV-2 RT-PCR Assay | [FDA Authorized](file:///C:\media\141538\download) | H |
| SML GENETREE Co., Ltd. Ezplex SARS-CoV-2 G Kit | Not FDA Authorized | H |
| Enzo Biochem, Inc Enzo AMPIPROBE® SARS-CoV-2 Test System | [FDA Authorized](https://www.fda.gov/media/139829/download) | H |
| Vela Operations Singapore Pte Ltd. ViroKey SARS-CoV-2 RT-PCR Test v2.0 | [FDA Authorized](file:///C:\media\140919\download) | H |
| GenMark Diagnostics, Inc. ePlex Respiratory Pathogen Panel 2 (ePlex RP2 Panel) | [FDA Authorized](file:///C:\media\142902\download) | H, M |
| NovaTec Immundiagnosticsa GmBH GSD NovaPrime® SARS-CoV-2 (COVID-19) RT-PCR | Not FDA Authorized | H |
| TAAG Genetics S.A. nPLEX SARS-CoV-2 Detection Kit | Not FDA Authorized | H |
| Illucidx Inc., Illucidx COVID-19 Dx RT-LAMP | Not FDA Authorized | H |
| BioZentech Co., Ltd., BZ QPCR COVID-19 Kit | Not FDA Authorized | H |
| T2Biosystems, Inc., T2SARS-CoV-2 Panel | [FDA Authorized](file:///C:\media\141752\download) | H |
| Molecular Epidemiology Inc., IEH SARS-CoV-2 RT-PCR Test | Not FDA Authorized | H |
| Suzhou PreciGenome, Ltd., Co., Fastplex Triplex SARS-CoV-2 Detection Kit (RT-PCR) | Not FDA Authorized | H |
| GK Pharmaceuticals Contract Manufacturing Operations, ACCU-RIGHT SARS-COV-2 RT-PCR KIT | [FDA Authorized](file:///C:\media\142307\download) | H |
| Detectachem Inc., MD-Bio BCC19 | [FDA Authorized](file:///C:\media\141788\download) | H |
| GUANGDONG ARDENT BIOMED Co., Ltd, Novel Coronavirus (COVID-19) Nucleic Acid Detection Kit (PCR-fluorescent Probe) | Not FDA Authorized | H |
| Nanjing Liming Bio-Products Co., Ltd., StrongStep® Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit | Not FDA Authorized | H |
| Hologic Aptima SARS-CoV-2 Assay Pooled Samples Workflow | [FDA Authorized](file:///C:\media\138097\download) | H |
| Hologic Panther Fusion SARS-CoV-2 Assay Pooled Samples Workflow | [FDA Authorized](file:///C:\media\136153\download) | H |
| DowGene Co., Ltd., Dow QuickFinderTM 2019-nCov Real-Time PCR Kit | Not FDA Authorized | H |
| Shimadzu Corporation, 2019 Novel Coronavirus Detection Kit | Not FDA Authorized | H |
| ProteomeTech Inc. GENEdania COVID-19 qRT-PCR | Not FDA Authorized | H |
| GenMark Diagnostics, Inc., eSensor SARS-CoV-2 Panel | Not FDA Authorized | H |
| Genetic Signatures Limited, EasyScreen™ SARS-CoV-2 Detection Kit (RP011 and RP012) | Not FDA Authorized | H |
| Eryigit medical Devices, Sentebiolab Senteligo SARS CoV-2 (COVID-19) Multiplex qPCR Detection Kit | Not FDA Authorized | H |
| Clinomics USA Inc., TrioDx RT-PCR COVID-19 Test | Not FDA Authorized | H |
| UStar Biotechnologies (Hangzhou) Ltd., EasyNAT® Diagnostic Kit for Novel-Coronavirus (COVID-19) RNA (Isothermal Amplification-Real Time Fluorescence Assay) | Not FDA Authorized | H |
| Genrui Biotech Inc, Novel Coronavirus (2019-nCoV) Nucleic Acid Detection Kit (RT-PCR) | Not FDA Authorized | H |
| AMSBIOInc., A+CheQ COVID-19 High-Speed RT-qPCR Detection Kit | Not FDA Authorized | H |
| TCM Bioscience, TCM-Q Corona III test | Not FDA Authorized | H |
| Todos Medical USA Inc., TODOS 2019-nCoV RT-qPCR Detection Kit | Not FDA Authorized | H |
| iCubate, Inc., iC-COVID-19 Assay | Not FDA Authorized | H |
| Sacace Biotechnologies s.r.1., SARS-CoV-2 Real-TM | Not FDA Authorized | H |
| Genes Laboratories, NEXdiaTM 2019-nCoV Detection Kit | Not FDA Authorized | H |
| Roche Molecular Systems Pooling Sample Workflow for the **cobas**® SARS-CoV-2 for use on the **cobas**® 6800/8800 Systems | [FDA Authorized](file:///C:\media\136046\download) | H, M |
| Caspr Biotech Corporation, Direct Caspr Lyo-CRISPR SARS-CoV-2 | Not FDA Authorized | H |
| Gerbion GmbH & Co. KG., Gerbion virellaSARS-CoV-2 seqc real time RT-PCR Kit 2.0 | Not FDA Authorized | H |
| Caspr Biotech Corporation, Caspr Lyo-CRISPR SARS-CoV-2 | Not FDA Authorized | H |
| General Biologicals Corporation, GB SARS-CoV-2 Real-Time RT-PCR | Not FDA Authorized | H |
| Sanigen Co. Ltd., Genelix™ COVID-19 Real-Time PCR Kit | Not FDA Authorized | H |
| Eurofins ARCA Technology, Inc., ARCA Straight Shot SARS-CoV-2 Extraction Free (EF) Assay | Not FDA Authorized | H |
| Biopoa, Co. Ltd., Rapid COVID-19 PoaCheck | Not FDA Authorized | H |
| RTA Laboratuvarlari Biyolojik Urunler Ilac ve Makine San. Tic. A.S., Diagnovital SARS-CoV-2 Multiplex | Not FDA Authorized | H |
| BIONEER Corporation, AccuPower SARS-CoV-2 Multiplex Real-Time RT-PCR Kit | Not FDA Authorized | H |
| Thermo Fisher Scientific, TaqPath™ COVID 19 High Throughput Combo Kit (also called "The Amplitude™ Solution with the TaqPath™ COVID 19 High Throughput Combo Kit") | Not FDA Authorized | H |
| DiaSorin Inc. LIAISON SARS-CoV-2 Ag | Not FDA Authorized | H |
| Ortho Clinical Diagnostics VITROS Immunodiagnostic Products SARS-CoV-2 Ag Assay (Reagent Pack / Calibrators) | Not FDA Authorized | H |
| Biosynex Rapid COVID-19 Antigen Test | Not FDA Authorized | H |
| CLINITEST Rapid COVID-19 Antigen Test | Not FDA Authorized | H |
| Healgen Rapid COVID-19 Antigen Test | Not FDA Authorized | H |
| Verasure Rapid COVID-19 Antigen Test | Not FDA Authorized | H |
| Aegle Rapid COVID-19 Antigen Test | Not FDA Authorized | H |
| LMSI, LLC d/b/a Lighthouse Lab Services, CovidNow SARS-CoV-2 Assay Kit | Not FDA Authorized | H |
| Ender diagnostics ag, Ender LAB COVID-19 isothermal PCR detection kit | Not FDA Authorized | H |
| LuminUltra Technologies Ltd., GeneCount® COVID-19 RT-qPCR Assay Kit | Not FDA Authorized | H |
| Biocartis NV, Idylla™ SARS-CoV-2 Test | Not FDA Authorized | H |
| QIAGEN QIAreach™ SARS-CoV-2 Antigen Test | Not FDA Authorized | H |
| Ender Diagnostics AG, Ender MASS COVID-19 isothermal PCR detection kit | Not FDA Authorized | H |
| Jiangsu Code Biomedical Technology Co. Ltd., CodeCheckSARS-CoV-2 RT-PCR Kit | Not FDA Authorized | H |
| Applied Biological Materials Inc. (abm), GenomeCoV19 Detection Kit | Not FDA Authorized | H |
| Meridian Bioscience Inc., Revogene® SARS-CoV-2 assay | Not FDA Authorized | H |
| BioGX Inc, Xfree COVID-19 Direct RT-PCR | Not FDA Authorized | H |
| LGC Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR Test | Not FDA Authorized | H |
| Merlin Biomedical (Xiamen) Co. Ltd., Novel Coronavirus (COVID-19) RT-PCR Kit | Not FDA Authorized | H |
| Sanwa BioTech Limited ALiA SARS-CoV-2 Antigen FIA Test | Not FDA Authorized | H |
| CardiAI Inc., CoviLampTM Fluorometric Test Kit | Not FDA Authorized | H |
| Chai Inc., COVID-19 Saliva Dx Test Kit | Not FDA Authorized | H |
| Genedrive Diagnostics Ltd., Genedrive ®96 SARS-CoV2 kit | Not FDA Authorized | H |
| Tetracore, Inc., EZ-SARS-CoV-2 Real-Time RT-PCR | Not FDA Authorized | H |
| BioGenex Laboratories, Inc., BGX COVID-19 RT-PCR | Not FDA Authorized | H |
| Beckman Coulter Access SARS-CoV-2 Antigen | Not FDA Authorized | H |

1 Settings for use include the following:

* H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
* M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
* W - Patient care settings operating under a CLIA Certificate of Waiver.